REMARKS

Claims 1 and 2 are pending in this application. Claim 2 is canceled without prejudice or disclaimer, and claim 1 is amended herein. Upon entry of this amendment, claim 1 will be pending. The Abstract and the Specification are also amended herein. Entry of this amendment and reconsideration of the rejections are respectfully requested.

No new matter has been introduced by this Amendment. Support for the amendments to the claims is discussed below.

The abstract is objected to by the Examiner. (Office action paragraph no. 4)

The abstract is objected to because the abstract contains 2 paragraphs. The abstract has been amended to be one paragraph.

The Specification is objected to. (Office action paragraph no. 5)

The Examiner notes that the specification lists sequences of the Sequence Listing without referencing their sequence identifiers. The specification has been amended to list the sequence identifiers corresponding to the listed sequence. The claims have also been amended to use the sequence identifiers.

Applicant respectfully notes that Examiner is incorrect in stating that no sequence listing has been filed. The sequence listing was filed on May 22, 2006, and the Notice of Missing Requirements dated February 9, 2007, acknowledged that the Biochemical Sequence Diskette (i.e., computer

readable form) was filed on that date. Applicant's amendments refer to this Sequence Listing, which is already of record.

Oath/declaration is objected by the Examiner. (Office action paragraph no. 6)

The Examiner states that the oath or declaration is defective because it does not identify the citizenship of the inventor Shiota Goshi. The objection is overcome by the attached Substitute Declaration.

Informalities are noted by the Examiner. (Office action paragraph no. 7)

The Examiner has two suggestions regarding the claims:

(i) claim 1-2 recite 'method comprised of;'. 'method comprising:' is suggested.

(ii) Claims 1 and 2 recited 'hTERT' and 'AFP'. Expansion of the abbreviations is suggested.

With regard to point (i), Applicant has amended the claims as suggested.

With regard to point (ii), Applicant notes that hTERT is a well known abbreviation, standing for Human Telomerase Reverse Transcriptase.

Claim 1 is rejected under 35 U.S.C. §102(b) as being anticipated by Kanaya et al. (Int. J. Cancer, Vol. 78, pp. 539-543, 1998). (Office action paragraph no. 8)

Reconsideration of the rejection is requested in view of the clarifying amendments to claim 1. Claim 1 has been amended to clarify the "process to obtain the sample containing RNA only," reciting that this comprises the steps of "obtaining a cell fraction from a body fluid" and "selectively extracting RNA from said cell fraction." Support for the recitation of "obtaining a cell fraction" may be found in the original wording of the claim and, for example, on page 11, lines 1-18, of the specification. Support for the recitation of "selectively extracting RNA from said cell fraction" may be found on page 10, lines 24-28, of the specification. For clarity, in the last clause in claim 1, the term "utilizing" has been amended to be "in the presence of." Support for conducting the PCR reaction in the presence of the dye may be found, for example, at page 12, lines 9-12, of the specification. Additionally for clarity, the last lines of claim 1 have been amended to recite "quantitatively measuring the fluorescence of the fluorescent dye binding to the PCR product." Support for quantitatively measuring the fluorescence may be found, for example, at page 12, lines 9-20, and at page 13, lines 6-10, of the specification.

The Examiner cites Kanaya as disclosing a cancer diagnostic method including "obtaining a sample containing RNA only as a somatic cell and cancer cell fraction from body fluid" at page 539, column 2, paragraph 2. The reference is cited as disclosing reverse transcription using the primers recited in claim 1 at page 540, col. 1, and which uses the SYBR green I fluorescent dye to bind to the PCR product.

With regard to the first process step in claim 1, the Examiner refers to p. 539, column 2, Materials and Methods paragraph 2, which discloses that tissue samples of renal cell carcinoma and

normal renal tissue were obtained, frozen, and then used for assays. These samples were washed with buffer and lysed and centrifuged, and the supernatant was apparently used for the analysis.

However, presumably, Kanaya's renal cell carcinoma samples are kidney hard tissue samples. As such, Kanaya does **not** disclose obtaining a cell fraction from a body fluid, as required by claim 1. In addition, the samples in claim 1 are extracted to contain RNA only. This does not appear to be the case in Kanaya.

In addition, claim 1, as amended, recites "a PCR reaction step in the presence of a fluorescent dye." The present specification on page 12, lines 9-12, for example, discloses performing the RT-PCR **in a single tube with the fluorescent dye**. This is different from Kanaya's procedure, in which the dye is used to stain a gel after electrophoresis.

In addition, Kanaya's detection does not appear to have been **quantitative**. Kanaya only detects the presence or absence of product (see Figure 1 on p. 541 and TABLE 1 on p. 542). Claim 1 recites "quantifying said PCR product," and has been amended to clarify that this is done by "quantitatively measuring the fluorescence of the fluorescent dye binding to the PCR product."

Claim 1, as amended, is therefore not anticipated by Kanaya. Applicants further submit that the method of claim 1 is not suggested by Kanaya. Furthermore, the invention of amended claim 1 is capable of detecting the evidence indicating the presence of cancer cells in early stage cancer in blood, which are commonly overlooked by any other methods, to allow eradication of the cancer

cells in an early stage. This is a distinctive and remarkable effect of the invention. Claim 1 is therefore also not obvious over Kanaya.

Claim 2 is rejected under 35 U.S.C. §103(a) as being unpatentable over Witzigmann et al. (Surgery, Vol. 131, pp. 34-43, 2002) in view of Lowe et al. (Nucleic Acids Research, Vol. 18, No. 7, page 1757-1761, 1990). (Office action paragraph no. 9)

The rejection of claim 2 is moot in view of the cancellation of claim 2 without prejudice or disclaimer.

If, for any reason, it is felt that this application is not now in condition for allowance, the Examiner is requested to contact the applicants' undersigned agent at the telephone number indicated below to arrange for an interview to expedite the disposition of this case.

In the event that this paper is not timely filed, the applicants respectfully petition for an appropriate extension of time. Please charge any fees for such an extension of time and any other fees which may be due with respect to this paper, to Deposit Account No. 01-2340.

Respectfully submitted,

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Enclosures: Petition for Extension of Time
Substitute Declaration

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